

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
24 April 2003 (24.04.2003)

PCT

(10) International Publication Number
WO 03/034213 A2

(51) International Patent Classification⁷: G06F 9/445

(21) International Application Number: PCT/US02/32822

(22) International Filing Date: 15 October 2002 (15.10.2002)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
09/978,599 16 October 2001 (16.10.2001) US

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(81) Designated States (*national*): AE, AG, AL, AM, AT, AU,
AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU,
CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH,
GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC,
LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW,
MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG,
SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VN,
YU, ZA, ZM, ZW.

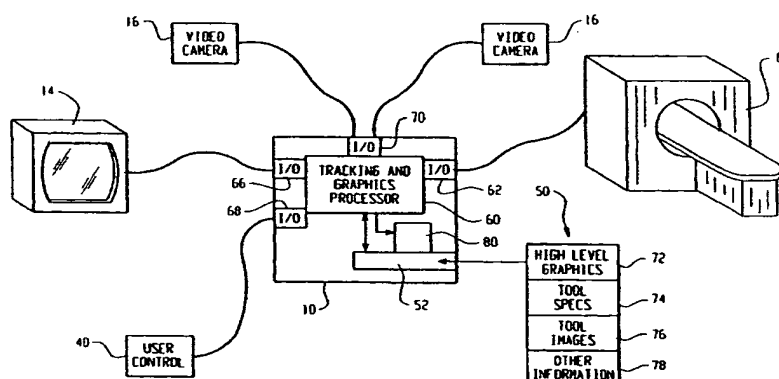
(84) Designated States (*regional*): ARIPO patent (GH, GM,
KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW),
Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM),
European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE,
ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, SK,
TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ,
GW, ML, MR, NE, SN, TD, TG).

Published:

— without international search report and to be republished
upon receipt of that report

For two-letter codes and other abbreviations, refer to the "Guid-
ance Notes on Codes and Abbreviations" appearing at the begin-
ning of each regular issue of the PCT Gazette.

(54) Title: DIGITAL MEDIUM ENHANCED IMAGE-GUIDED PROCEDURE SYSTEM AND METHOD



(57) Abstract: A software-integrated disposable kit (20) contains a series of sterile packages which hold instrumented tools (26, 28, 30), accessories (42, 44, 46) which are implanted or used during a procedure, peripherals (40) e.g., mouse, keyboard, etc., for a user input control (34) for controlling a computer (10), markers (32) which are tracked by a tracking system (16), all in sterile condition, and a one time use digital medium (50). When an image-guided procedure is to be performed, the digital medium is inserted into the computer (10) and the user interface is displayed. The digital medium stores a portion of the software which, in combination with software on the computer, provides all of the software necessary for full user functionality, which includes display of selected diagnostic image information, tracking of the instruments, and superimposition of the virtual representations of the tools on the images, descriptions, specifications and characteristics of the specific tools in the kit, and 3D virtual representations or images of the instrumented tools for wire frame or rendered display of the tools (14). At the end of a procedure, the digital medium is deactivated or encrypted (80). The digital medium and the used tools are then disposed of without reuse. The system allows the user to save relevant information obtained from the procedure, e.g., images, notes, etc. on the digital medium which is encrypted against reuse and archived.

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**DIGITAL MEDIUM ENHANCED IMAGE-GUIDED PROCEDURE
SYSTEM AND METHOD**

Background of the Invention

The present invention relates to the art of image guided procedures. It finds particular application in conjunction with neurosurgical and orthopedic procedures and will be described with particular reference thereto. However, it is to be appreciated that the present invention is equally applicable to a wide range of image guided procedures in industrial applications, manufacturings, computer programs and games, video and audio disk players, as well as in human and veterinary surgically and minimally-invasive procedures.

Heretofore, images of a region of a patient in which surgery is planned have been made using magnetic resonance imaging systems, computed tomography, or other similar imaging modalities. These techniques generate a substantial amount of data, which is then manipulated through software to provide three-dimensional guidance within the imaged region. Typically, to facilitate diagnoses and treatment through image guidance, this data is manipulated using a computer supplemented with other specialized computer hardware to display selected views during surgery, e.g., orthogonal views, slices, perspective renderings, or the like.

Acquired images used for image guided surgery typically use anatomical reference markers which are commonly imaged with the patient. At the surgical site, acoustic,

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infrared, video camera, or other tracking technologies are utilized to determine the location of the markers relative to the patient and the surgical site. Additional computer software is provided to register the coordinate system of the markers, hence the patient, with the image(s). Thereafter, the same system is used to monitor the current position of surgical tools instrumented with similar markers, and coordinate their position in physical space with their position in the image(s). In this manner, the current position of the tool or probe relative to obscured portions of the patient's anatomy is readily determined. This facilitates implementing minimally invasive techniques by allowing the surgeon to use the acquired image(s) to see below the visible surface of the patient. For example, the surgeon can use the software's graphic user interface to mark the entry point and proposed trajectory of a pedicel screw on a patient's spine. The marked image(s) can then be used to enable the surgeon to follow the trajectory created below the surface with the instrumented surgical tool to be sure that the screw will not impinge the spinal cord and that it will engage sufficient bone to anchor properly, and the like.

In prior image guided surgery systems, different tools have been used for different portions of the human anatomy. To accommodate the use of different tools, the surgeon typically needs to calibrate the tool to the system. That is, the system needs to know the length, diameter, distances between various portions of the tool and the markers mounted on the tool, relative locations of markers and a tool axis, and the like. Prior image guided surgery systems did not allow use of non-instrumented or standard surgical tools. Also, in prior image guided surgery systems, as new tools are developed or as tools are modified, information about the tools loaded into the system must be reloaded on the entire installed base. Similar reinstallation problems occur when improvements are made to the software.

Prior image guided surgery systems also relied on reusable surgical tools. This has several drawbacks. First, with use, tools with cutting edges become dull. Second, since the tools are sterilized between uses, infection to the patient

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is possible due to a potential failure of the sterilization procedure.

Typically, image guided surgery systems are universal, i.e., applicable to any portion of the human anatomy that can be clearly imaged with reference markers. Computer software is provided to handle the imaging and alignment needs in virtually any region of the human anatomy. In some instances, the image guided surgery software is incorporated directly into the diagnostic imaging device. In other instances, additional expensive hardware is provided separately.

Prior image guided surgery systems have also relied on a capital equipment sales model, which has resulted in limited market acceptance. Prior image guided surgery systems have been large in size and cost-prohibitive for most. The shipping logistics has been expensive and cumbersome.

Image-guided tools have also been used in various industrial and manufacturing applications. For example, in environments which are hostile to human operators, such as areas of high radiation, tools have been manipulated remotely while an operator views images on a screen.

The present invention contemplates a new and improved method for image guided surgery, which overcomes the above-referenced problems and several others.

Summary of the Invention

In accordance with one aspect of the present invention, a system includes a computer for displaying images on a display. The computer is programmed with limited functionality. A single-use digital medium contains software to upgrade the computer temporarily to higher user functionality for a preselected procedure. A means disables the software from being reused to upgrade the computer after the preselected procedure.

In accordance with another aspect of the present invention, a digital medium is removed from a kit and inserted into a computer which has limited functionality. The software on the computer is temporarily upgraded with software from the

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digital medium. After the procedure, the digital medium is deactivated or encrypted against reuse in the computer.

One advantage of the present invention resides in low or no capital cost to facilities for the equipment.

5 Another advantage of the present invention is that it enables automatic upgrade of the image guided procedure software and of the specifications, descriptions, and characteristics of the tools residing on the computer upon insertion of the digital medium.

10 Yet another advantage of the present invention is the assured sterility of the tools, accessories, and any other components of the system contained in the software-integrated disposable kit, which enter the sterile field.

15 Another advantage of the present invention is the assured sharpness and reliable maintenance of any other quality aspects of the tools and guides.

Another advantage includes simplified customer billing.

20 Still further advantages of the present invention will become apparent to those of ordinary skill in the art upon reading and understanding the following detailed description of the preferred embodiments.

Brief Description of the Drawings

25 The invention may take form in various components and arrangements of components, and in various steps and arrangements of steps. The drawings are only for purposes of illustrating a preferred embodiment and are not to be construed as limiting the invention.

30 FIGURE 1 is a perspective view of a mobile cart in combination with a computer with peripherals including but not limited to a joystick, a display, accessories including but not limited to cables, and a tracking system in accordance with the present invention;

35 FIGURE 2 is a perspective view of a software-integrated disposable kit in accordance with the present invention; and,

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FIGURE 3 is a diagrammatic illustration of a schematic for the computer in accordance with the present invention.

Detailed Description of the Preferred Embodiments

5 Although described with reference to surgical applications, it is to be appreciated that the present invention has numerous other applications beyond the treatment of human patients. Such applications include computer programs or games, DVDs, CDs, and the like which are limited to a single or other
10 specified number of uses. With reference to FIGURE 1, one embodiment of the invention mentioned herein includes a computer 10 that is mounted in a mobile cart 12 or other convenient location in a surgical suite outside of the sterile field. This may be on the wall or on a hospital cart that is not in use.
15 In the illustrated embodiment, as the computer 10 is inserted into the cart, a series of electrical interconnections are made, including interconnection with a display e.g., a flat screen monitor 14, interconnection with an electrical wall outlet, backup power supply unit contained within the cart, or some
20 combination thereof, interconnection with one or several tracking system cameras 16, and the like. The tracking system cameras 16 for tracking the location of markers including but not limited to acoustic sensors, infrared sensors, and the like, are mounted on mobile carts, suspended from the ceiling of the
25 surgical suite, mounted in conjunction with other equipment in the surgical suite such as the lighting, the operating table, or the like. In one embodiment, the cart 12 includes a port for connecting the computer 10 with the central record storage system of the hospital via a network, a diagnostic imaging
30 device 64, or other source of electronic images of the patient. In other embodiments, the computer 10 includes a disk, tape, or other media drive for receiving the image information via a portable medium.

35 With reference to FIGURE 2, for each surgical application, there is a corresponding software-integrated disposable kit 20. The kit 20 includes a sealed,

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e.g., shrink-wrapped, carry-case or unit 22 which contains all of the necessary equipment for performing a specific surgical procedure indicated on a label 24 on the outside of the kit. A variety of kits 20 are provided, each labeled for a specific surgical procedure or limited group of closely related surgical procedures. Each kit 20 typically includes the appropriate surgical tools for the corresponding procedure, such as instrumented drill guides 26, 28, instrumented probes 30, and other accessories as may be appropriate to the selected procedure. The tools are instrumented with markers 32 which are tracked by the cameras 16, in the preferred embodiment. Additional markers 32 not attached to a tool may be included in the kit 20. In other embodiments, the markers 32 are acoustic or infrared transmitters whose signals are received by corresponding acoustic or infrared cameras 16. By tracking the markers 32 with one or several cameras 16, the current location of each marker 32, hence the associated tool, is readily determined by well-known triangulation techniques. In other embodiments, more than two cameras 16 or other sensors are provided for improved tracking even when the surgeon temporarily blocks access to one of the markers 32. Each of the drill guides 26, 28, probes 30, and other surgical tools and accessories are presterilized and wrapped in peel-open or other sterile packaging.

The kit 20 further includes several other components which are commonly used during image guided surgery. These components can include a universal tool tracker 34 which is mounted directly to a fixed location on the tool. The universal tool tracker 34 is used to track standard surgical tools that are not included as part of the kit 20. A registration phantom 36 that is attached to the operating room table or directly to the imaging device is also included and is used to register an acquired image(s) to the patient's anatomy. Depending on the surgical procedure, other components may be included such as a head frame 38 with markers for attachment to the patient. All

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the components contained in the kit 20 are again presterilized and prepackaged in sterile packaging.

The kit 20 further includes, but is not limited to, a user input device(s) 40 such as a joystick, mouse or keyboard with which the operator controls the software's graphic user interface. The user input device(s) 40 and their associated cable(s) are sterile and packaged in sterile packaging. During set-up for the procedure, the sterile packaging is opened and the cable(s) for the user input device(s) 40 is plugged into a corresponding port on the computer 10 or mobile cart 12. Another embodiment includes a wireless user input device(s) that is recognized by the system, through an infrared port for example on the computer 10 or mobile cart 12.

The kit 20 can further include implants 42 and other surgical accessories that are used in the selected surgical procedure. For example, the kit 20 can include pedicel screws 42, rods 44, and mounting clamps 46, and the like as are appropriate for a surgical procedure on the spine. Different surgical procedures will, of course, have different surgical accessories in the kit 20. The surgical accessories are sterile and sealed in sterile packaging.

The kit 20 further includes a one-time-use digital medium 50, such as a small high-capacity diskette, CD-ROM, DVD, or the like. The digital medium 50 is configured to be received into a drive 52 in the computer 10. The diskette 50 contains a portion of the software to be used during a surgical procedure, image processing algorithms specific to the application, dimensions and other specifications of the surgical tools and accessories in the kit 20, and other information of use during the surgical procedure.

With reference to FIGURE 3, the computer 10 may include triangulation or tracking software and base or low-level graphics and other processing software 60. A video-grabber card or other similar input/output device for capturing still-images or live video includes an input/output port and/or interface 62 for receiving electronic images directly from an imaging device

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64. Images can also be received through the computer network port by accessing central record keeping via the hospital's network. Optionally, the computer 10 may include a drive for reading the electronic image information obtained from the imaging device 64 from disk, tape, or other similar media. The computer 10 also includes a graphics card or the like with a port and/or interface 66 for connecting to the display 14. Likewise, the computer 10 includes a port and/or interface 68 for interconnection with the user input device 40. The computer 10 may also contain a port, an infrared port for example, for wireless connection to the user input device(s). The computer 10 further includes a port and/or interface assembly 70, which interfaces the tracking system's cameras 16 with the tracking software.

The one-time-use digital medium 50, in the preferred embodiment is a mini-diskette, which includes information useful for a specific surgical application. The medium contains an area for high-level graphics processing software 72 with the most recently revised algorithms for the graphics processes which are specific to the selected surgical procedure. The disks for different surgical procedures may have different high-level graphics processing software and information. The high-level graphics processing software 72 interacts with the low-level graphic processing software 60 to enable the computer 10 to perform the image and graphics processing which it may be called upon to perform during the selected surgical procedure. Various other electronic keys, including media such as CD-ROM and DVD for example, for enabling the computer 10 for image guided surgery are also contemplated.

The digital medium 50 further includes an area 74 for software which describes tool specifications. That is, software to describe the specifications of each of the tools, probes, guides, and any other necessary accessories in the kit. In conjunction with the tool(s) physical specifications, markers 32, and the tracking system's cameras 16, the image guided surgery software recognizes the tool and correlates its position, trajectory, end point, and any other necessary

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characteristics in physical space with it's virtual representation on the display 14.

The digital medium 50 further includes an area 76 for 3D virtual representations, images, or information, in VRML format for example, of the instrumented tools contained in the kits. These files are used to create 3D virtual representations of each of the surgical tools. The 3D representations of the tools are superimposed on each acquired and registered image. These representations can be in wireframe or fully rendered format, for example, depending on the surgeon's preference. The 3D surgical tool information or image area 76 is accessed by the software on the computer and the digital medium and manipulated so the tools virtual representation in the image(s) is correlated to its 3D position in physical space as determined by the camera(s) 16.

The digital medium 50 further includes an area 78 for software that describes other information such as instructions with guides concerning common steps taken during the surgical procedure. For example, this section may include software information concerning the depth and diameter of the holes to be tapped for the surgical screws in the kit. It may include information or guidelines for the use or placement of the accessories in the kit, images from a previous or similar procedure, anatomy atlas tables containing information on certain anatomical angles and distances specific to an application, and the like. This portion of the digital medium 50 may also include software for upgrading the low-level graphics processing software 60 to the latest released revision.

The invention further includes a means 80 to ensure one-time-use of the digital medium 50. This means preferably resides in the computer 10. In one embodiment, this means erases all or part of the digital medium at the end of the procedure. Alternately, the software is encrypted to block reuse. In another embodiment, the digital medium 50 is physically deformed to prevent reuse. After the procedure, the tools and the digital medium 50 are disposed. Alternatively, the tool and the medium 50 are returned to the company for

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inspection, remanufacture, cleaning, sterilization, and/or repackaging. Alternatively, the digital medium can also be used to store data obtained during surgery i.e., notes, images, etc. In this case, the digital medium 50 is archived.

5 In a preferred marketing procedure, the computer 10 is of limited cost. The computer 10 is sold to the hospitals at nominal or no cost. The cost of the computer 10 is recovered by the sale of the single use kits 20, the price of which is gauged to cover the cost of maintaining the computer 10 as well
10 as the tools and accessories. This business model eliminates the traditional capital equipment sale process for conventional image guided surgery equipment. It also facilitates patient billing.

15 In one alternate embodiment, the digital medium is a computer game which is deactivated after a fixed number of uses, e.g., one. In another embodiment, the digital medium is a computer program for other than surgical procedures, such as software for business or manufacturing purposes, personal finance, and the like. The present technique is useful for
20 enabling potential purchasers to try new software before deciding whether to buy it. In another embodiment, the digital medium carries a movie or other video program for limited time viewing. In yet another embodiment, the digital medium is a CD with a limited number of plays.

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Having thus described the preferred embodiment, the invention is now claimed to be:

1. A system having a human-viewable display (14), and a computer (10) for displaying and manipulating images on the display, characterized by:
 - the computer being programmed with limited
5 functionality;
 - a single-use digital medium (50) containing software to upgrade the computer temporarily to higher user functionality for a preselected procedure; and,
 - a means (80) for disabling the software from being
10 reused to upgrade the computer after the preselected procedure.
2. The system as set forth in claim 1, further including a software-integrated disposable kit (20) including:
 - the digital medium with procedure specific upgrade
software; and,
 - 15 tools (20, 30, 34) instrumented (32) to be tracked by the tracking system.
3. The system as set forth in claim 2 further including:
 - a tracking system for tracking system for tracking
20 movement of the tools, the tracking system communicating with the computer to provide the computer with information for superimposing designations of the tools on displayed images.
4. The system as set forth in any one of claims 1-3 wherein the computer is preprogrammed with:
 - 25 a portion of a procedure that provides minimal user functionality, full user functionality being enabled by procedure specific upgrade software obtained from the digital medium (50).
5. The system as set forth in any one of claims 1-
30 4, further including:

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a mobile cart (12) that holds at least the computer (10), display (14), and standard peripherals (40).

6. The system as set forth in any one of claims 1-5 wherein the computer (10) includes:

5 a drive (52) which receives and reads the digital medium (50).

7. The system as set forth in any one of claims 1-6, further including:

10 a means (80) for deactivating or encrypting the digital medium against reuse at the end of a surgical procedure.

8. The system as set forth in any one of claims 1-7, wherein the computer includes:

an input/output interface (62) for capturing still-images and/or live video from an imaging device (64);

15 a graphic input/output interface (68) for connecting to the display (14);

an interface (68) for interconnection with at least one of a wired user input device (40) and a wireless user input; and,

20 an interface (70) for interconnection with tracking sensors (16) for monitoring position and movement of the instrumented tools.

9. The system as set forth in any one of claims 2-8 where in the software-integrated disposable kit (20) further includes:

25 a label (24) to identify a particular procedure to be performed using the kit;

sterile packaging (22) in which the tools are contained in sterile condition;

30 other accessories (36, 38, 42, 44, 46) in sterile condition in sterile packaging;

a user input device (40); and

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wherein the digital medium (50) is a disposable one-time use digital medium readable by the computer and contains an upgrade software specific to the procedure identified on the label.

5 10. The system as set forth in claim 9 wherein the user input devices include:

a disposable, sterilizable, wireless peripheral (40) for use at the procedure site for remote communication with the computer.

10 11. The system as set forth in any one of claims 1-10 wherein the digital medium includes:

a preprogrammed one-time use application specific software module (72, 76) to be used in the procedure; and

15 a preprogrammed software module (74, 76) describing the tools, implants, and other accessories.

12. The system as set forth in any one of claims 1-11 wherein the digital medium includes:

20 preprogrammed software (74) describing dimensional specifications of each of the tools, probes, guides, and any other instrumented accessories contained in the kit.

13. The system as set forth in any one of claims 1-12 wherein the digital medium includes:

25 preprogrammed software (76) with 3D virtual representations, images, or information or instrumented tools, accessories, implants, and any associated hardware contained in the kits used to create 3D virtual representations of the tools in the images on the display.

14. The system as set forth in any one of claims 1-13, the digital medium includes:

30 preprogrammed software (72) for superimposing instrumented tools, accessories, implants, and associated

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hardware on the images in a wireframe or a user selected custom format.

15. The system as set forth in any one of claims 1-14 wherein the digital medium includes:

5 an area (72) which stores the software application which enables full user functionality;

an area (74) which stores specifications and characteristics of the tools;

10 an area (76) which stores 3D virtual representations, images, or information of the tools and accessories contained in the kit; and

an area (78) which stores additional information relevant to a particular procedure.

16. The system as set forth in any one of claims 1-15 wherein the tracking system includes:

one of acoustic sensors, infrared sensors, video cameras (16), that are utilized to determine a location of the tools.

17. The system as set forth in claim 16 wherein the tracking system includes:

20 a mobile cart (12) for positioning the video cameras in a surgical suite.

18. The system as set forth in any one of claims 1-17 wherein the processor includes:

25 an interface for interconnection with a source of three-dimensional electronic diagnostic images;

an interface for interconnection with a human-readable display for displaying diagnostic images and superimposed representations of the tools;

30 an interface for interconnection with a user input control; and,

an interface for interconnection with optical sensors for monitoring position and movement of the tools.

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19. A kit for use in the system of claims 1-18, the kit comprising:

an identification of a surgical procedure to be performed using the kit;

5 the surgical tools in sterile condition in sterile packaging which are used in the identified surgical procedure;

medical appliances in sterile condition in sterile packaging which are used in the identified surgical procedure;

10 an operator control in sterile condition in sterile packaging for electrical interconnection with a graphics processor outside a sterile field; and

the digital media preprogrammed with a portion of an image guided surgery processing program and descriptive information concerning the tools and the appliances in the kit
15 which is readable by the processor.

20. A method of implementing a computer-implemented procedure, the method comprising:

opening a software-integrated disposable kit (20) and removing a digital medium (50) with a procedure specific
20 software which temporarily upgrades limited functionality software to higher user functionality;

inserting the digital medium into a computer (10) which is preprogrammed with the limited functionality software to upgrade the functionality;

25 performing the procedure;

deactivating or encrypting the digital medium against reuse in the computer;

removing the digital medium from the computer.

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21. The method as set forth in claim 20 further including:

5 archiving on the digital medium a record or history of the performed procedure, including the downloaded images, selected instruments, implants, length of procedure time, notes, or other relevant information obtained during the procedure.

22. The method as set forth in claim 21 further including:

replaying archived data for review and follow-up.

10 23. The method as set forth in any one of claims 20-27 further including:

prior to placing the digital medium in the kit, programming the digital medium with dimensional information about and depictions of tools contained in the kit.

15 24. The method as set forth in claim 23 further including:

preventing reuse of the tools.

25. The method as set forth in claim 24 further including:

20 disposing of the tools and the digital medium without reuse after the procedure.

26. The method as set forth in any one of claims 20-25 further including:

25 using the computer as a planning station before a procedure to define entry points and trajectories.

27. The method as set forth in any one of claims 20-26 further including:

prior to placing tools and accessories in the kit, sterilizing the tools and accessories.

30 28. An image guided procedure system comprising:

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a set of tools which are instrumented to be tracked during image guided surgery;

5 a processor which is preprogrammed with less than all of the software which is used for manipulating images during the image guided procedure and for tracking the movement of the instrumented surgical tools during the image guided procedure;

10 a digital media which is preprogrammed with a remaining portion of the software for processing the image data and tracking movement of the instrumented tools and with descriptive information.

29. The system as set forth in claim 28 wherein the processor further includes:

a deactivator which deactivates the digital media against reuse at the end of an image guided procedure.

15 30. A method comprising:

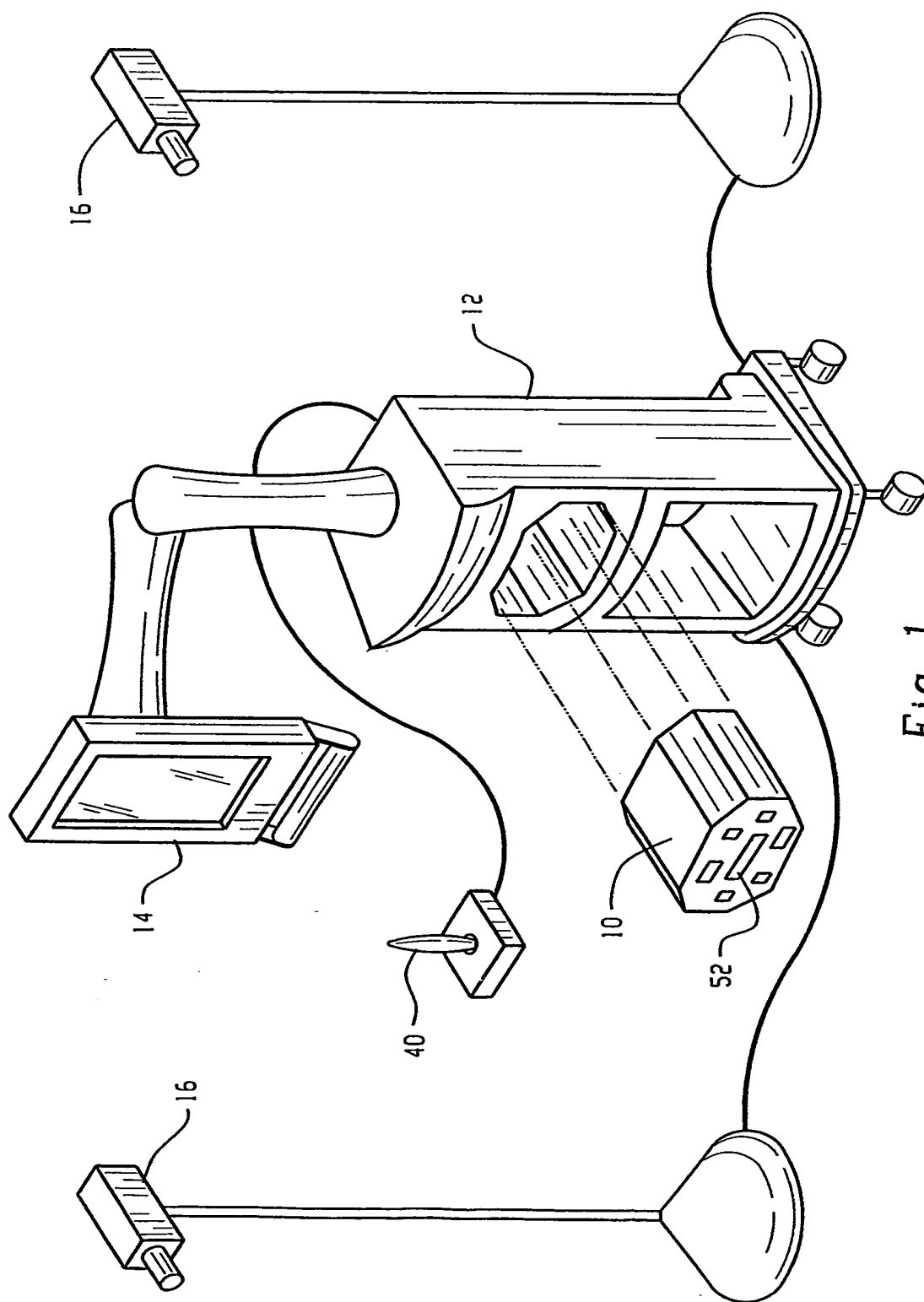
providing a kit which includes (1) tools and accessories and (2) a digital medium which is preprogrammed with (i) at least a portion of a graphics processing program and (ii) information concerning the tools and accessories;

20 at a procedure site, removing the secure digital medium from the kit and inserting it into a processor which, between software with which the processor is preprogrammed and the software from the digital medium, processes electronic images, correlates a coordinate system of the procedure site with a coordinate system of the diagnostic images, tracks a location of the instrumented surgical tools in the coordinate system of the procedure site, and translates the instrument position into the coordinate system of the diagnostic image.

25 31. The method as set forth in claim 30 further including:

30 after the procedure, deactivating the digital media against reuse.

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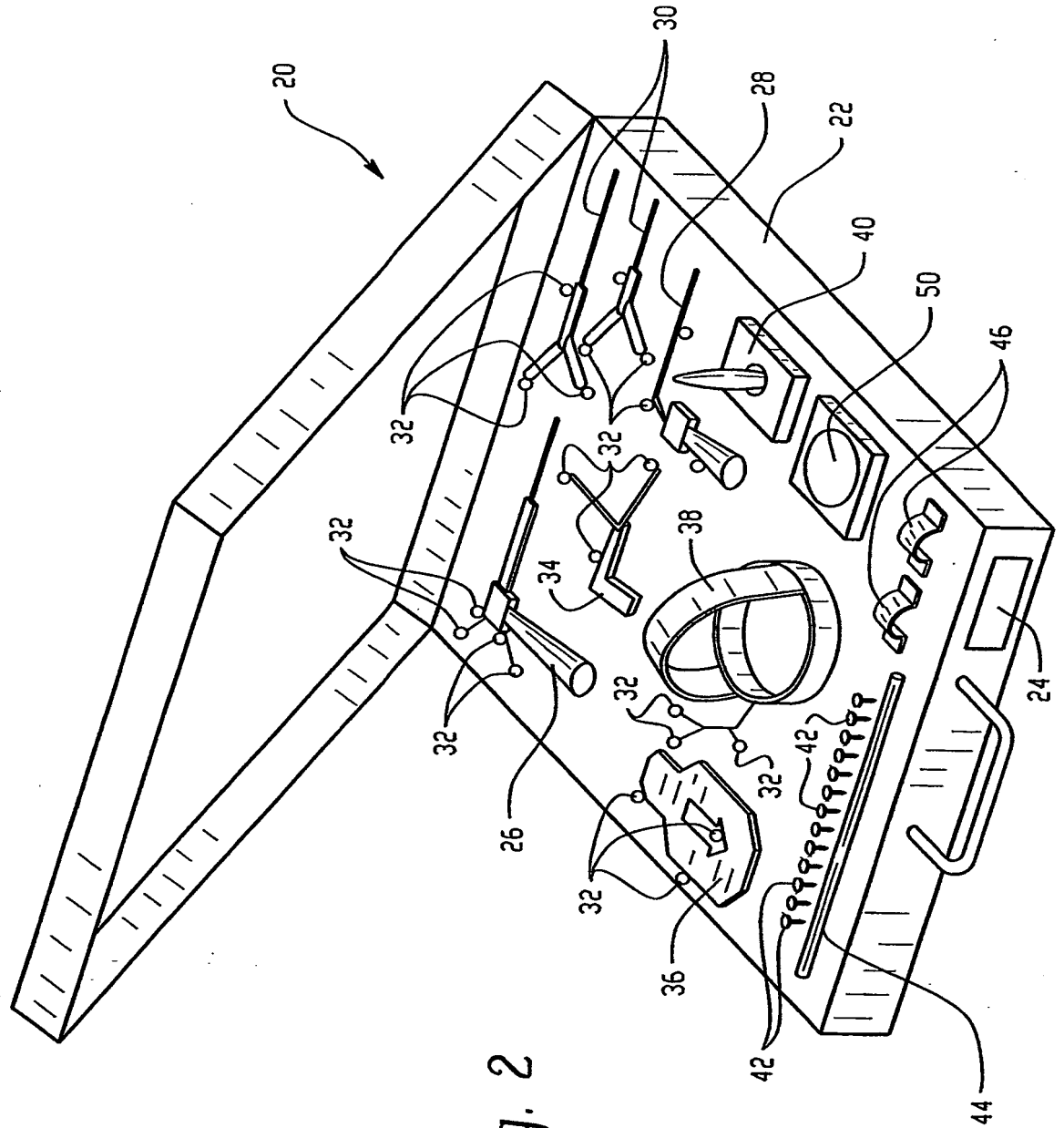


Fig. 2

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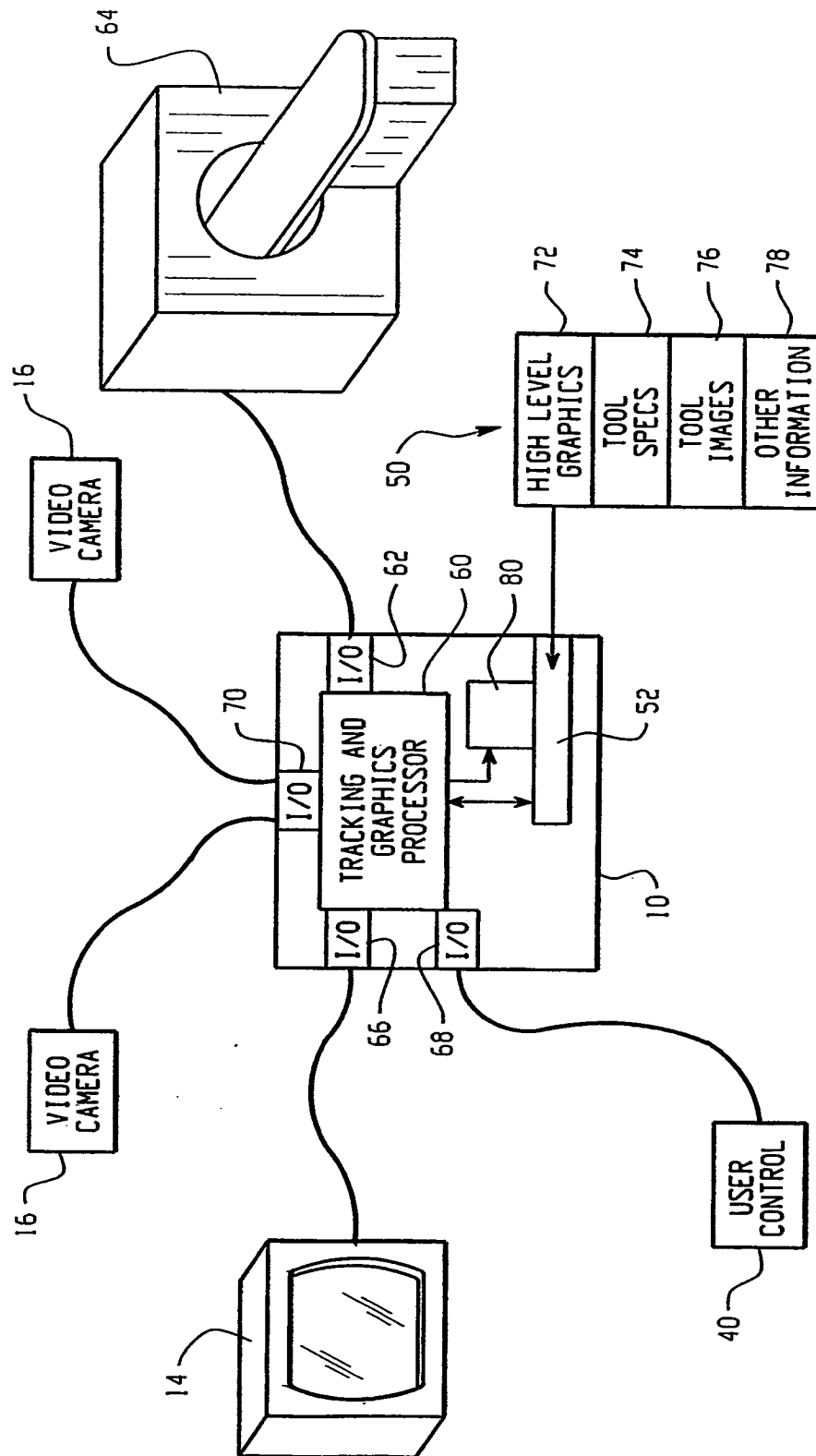


Fig. 3

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(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
24 April 2003 (24.04.2003)

PCT

(10) International Publication Number
WO 2003/034213 A3

(51) International Patent Classification⁷: **G06F 9/445**,
1/00, 21/00

(21) International Application Number:
PCT/US2002/032822

(22) International Filing Date: 15 October 2002 (15.10.2002)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
09/978,599 16 October 2001 (16.10.2001) US

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(81) Designated States (national): AE, AG, AL, AM, AT, AU,
AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU,

CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH,
GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC,
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SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VN,
YU, ZA, ZM, ZW.

(84) Designated States (regional): ARIPO patent (GH, GM,
KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW),
Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM),
European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE,
ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, SK,
TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ,
GW, ML, MR, NE, SN, TD, TG).

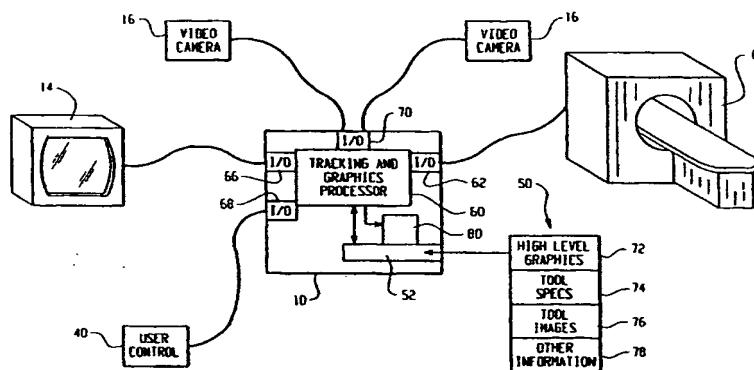
Published:

- with international search report
- before the expiration of the time limit for amending the
claims and to be republished in the event of receipt of
amendments

(88) Date of publication of the international search report:
18 March 2004

For two-letter codes and other abbreviations, refer to the "Guid-
ance Notes on Codes and Abbreviations" appearing at the begin-
ning of each regular issue of the PCT Gazette.

(54) Title: DIGITAL MEDIUM ENHANCED IMAGE-GUIDED PROCEDURE SYSTEM AND METHOD



(57) Abstract: A software-integrated disposable kit (20) contains a series of sterile packages which hold instrumented tools (26, 28, 30), accessories (42, 44, 46) which are implanted or used during a procedure, peripherals (40) e.g., mouse, keyboard, etc., for a user input control (34) for controlling a computer (10), markers (32) which are tracked by a tracking system (16), all in sterile condition, and a one time use digital medium (50). When an image-guided procedure is to be performed, the digital medium is inserted into the computer (10) and the user interface is displayed. The digital medium stores a portion of the software which, in combination with software on the computer, provides all of the software necessary for full user functionality, which includes display of selected diagnostic image information, tracking of the instruments, and superimposition of the virtual representations of the tools on the images, descriptions, specifications and characteristics of the specific tools in the kit, and 3D virtual representations or images of the instrumented tools for wire frame or rendered display of the tools (14). At the end of a procedure, the digital medium is deactivated or encrypted (80). The digital medium and the used tools are then disposed of without reuse. The system allows the user to save relevant information obtained from the procedure, e.g., images, notes, etc. on the digital medium which is encrypted against reuse and archived.

WO 2003/034213 A3

Inter al Application No
PCT/US 02/32822

According to International Patent Classification (IPC) or to both national classification and IPC

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 G06F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, IBM-TDB, INSPEC, COMPENDEX

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 119 886 A (CII HONEYWELL BULL) 26 September 1984 (1984-09-26) page 1, line 1 -page 6, line 24 page 2, line 1 -page 2, line 29 page 14, line 22 -page 16, line 10 ---	1,20,28, 30
A	US 5 138 712 A (CORBIN JOHN R) 11 August 1992 (1992-08-11) column 1, line 1 -column 3, line 24 ---	1-31
A	US 5 553 143 A (TAYLOR NEIL W ET AL) 3 September 1996 (1996-09-03) column 1, line 1 -column 2, line 17 -----	1-31

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Date of the actual completion of the international search

17 December 2003

Date of mailing of the international search report

22/01/2004

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Lo Turco, S

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US 02/32822

Patent document cited in search report		Publication date		Patent family member(s)	Publication date
EP 0119886	A	26-09-1984	FR	2541014 A1	17-08-1984
			AT	30976 T	15-12-1987
			DE	3467646 D1	23-12-1987
			EP	0119886 A1	26-09-1984
			JP	1922860 C	07-04-1995
			JP	6044229 B	08-06-1994
			JP	59157747 A	07-09-1984
US 5138712	A	11-08-1992	CA	2025434 A1	03-04-1991
			GB	2236604 A ,B	10-04-1991
			HK	48594 A	27-05-1994
			JP	2928949 B2	03-08-1999
			JP	4100148 A	02-04-1992
			SG	2494 G	10-06-1994
US 5553143	A	03-09-1996	AU	687058 B2	19-02-1998
			AU	6731794 A	17-08-1995

Form PCT/ISA/210 (patent family annex) (July 1992)

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